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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,076	10/23/1998	SUSAN ADELE GREENFIELD	263/PPIR2548	8070

7590 05/14/2004

WENDEROTH LIND & PONACK
2033 K STREET N W SUITE 800
WASHINGTON, DC 20006

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,076

Applicant(s)

GREENFIELD ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16 and 30-38 is/are pending in the application.
4a) Of the above claim(s) 34-38 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 13, 16, 30, 31 and 33 is/are rejected.
7) ☒ Claim(s) 32 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The amendment filed 3-3-04 has been entered into the record and has been fully considered.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.
4. Claims 13, 16 and 30-38 are pending.

Election/Restrictions

5. Applicant's election of Group I, claims 13, 16 and 30-33 drawn to the peptide of SEQ ID NO:1 and first method of use in a method of making an antibody in the Paper of 10-7-03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
6. Claims 34-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper of 10-7-03.
7. This application contains claims 34-38 drawn to an invention nonelected with traverse in the Paper of 10-7-03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Rejection of claims 13, 16, and 30-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn based upon Applicant's claim amendments.

As previously set forth, "the claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Amended claim 13 newly recites the negative limitation "having no cholinesterase activity." However, the Examiner fails to find support for such recitations in the isolated peptide as instantly claimed. Applicant's should provide support for the recitation by page and line number within the specification as originally filed. The previous art rejections over full length acetylcholinesterase have been withdrawn based upon the negative limitation. However, it would appear that the art rejection may be reinstated upon cancellation of the new matter from the claim."

Rejections Reinstated

Claim Rejections - 35 USC 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 13, 16, 30-31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Soreq et al., US Patent No. 5,932,780, filed Jan. 9, 1995 and issued August 3, 1999.

Soreq et al., teach SEQ ID Nos:7, 8 and 25 which correspond to isolated C-terminal (Exon 6) peptides of acetyl-cholinesterase, (AChE). The peptides are partial fragments of acetylcholinesterase and consist of 40-45 amino acids in length. The peptides comprises SEQ ID NO:1 in full, see in particular residues 12-25 of SEQ ID NO:25, residues 17-30 of SEQ ID NO:7 and residues 17-30 of SEQ ID NO:8 and Figure 6. In addition, column 8, lines 9-20 teaches biologically active analogs of such sequences. The Soreq reference is silent with respect to the calcium channel modulatory function of the peptides, however it is noted that as the structural limitations of the peptides are met by Soreq et al., the functional limitations are deemed inherent absent convincing factual evidence to the contrary. It is further noted as set forth above in column 8, lines 9-20 that since the biological (enzymatic) activity of the Soreq peptides is retained and the biological activity of the full length enzymatic AChE molecule includes mediation of calcium influx as disclosed in applicants specification at p. 11, lines 20-25, the Soreq peptides are also deemed to retain mediation of calcium influx to cells. Soreq teaches various means of analysis of expression including with

labeling of AChE via antibody immunoreactivity and wherein the enzyme may be analyzed through immobilization on solid support such as via Elisa format or In situ immunohistochemistry of tissue with antibodies immunoreactive to AChE generated via immunization with AChE peptides, see in particular columns 8, 25-52, and Figures 8-15, and 18-28. The peptides are fragments of acetylcholinesterase and include chemically synthesized molecules including recombinantly produced molecules. Thus, the reference teachings anticipate the claimed invention.

Status of Claims

12. No claims are allowed.

Allowable Subject Matter

13. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In the claim, "is" is interpreted as "consisting of".

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

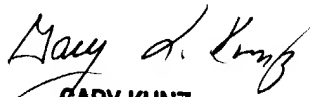
15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.

Sharon L. Turner, Ph.D.
May 4, 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600